to vary by the academic centre appraising the submission, reflecting the inherent objectivity and uniform implementation of NICE methodology.

PHP118

CAN INDIVIDUAL HEALTH TECHNOLOGIES IMPROVE OVERALL CHRONIC DISEASE MANAGEMENT?

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OBJECTIVES: Chronic disease is resource intensive for health care systems. Considerable efforts have focused on the management of chronic disease in the community setting however the role of individual health technologies is often overlooked. The purpose of this analysis was to identify examples of individual health technologies that contribute to overall chronic disease management. **METHODS:** The Medical Advisory Secretariat (MAS) in Ontario has published a substantive body of evidence-based analyses on health technologies. The MAS Ontario Health Technology Assessment Series was searched for reports published between 2006 and 2011. Findings were limited to analyses that reported on health technologies with moderate to high quality evidence of effectiveness for chronic disease management. Outcomes of interest included health resource utilization, patient and clinical outcomes, and economic analyses measures. **RESULTS:** Two technologies had direct evidence of the cure of chronic disease. Bariatric surgery was effective in the resolution of diabetes among morbidly obese adults (77% resolution; 95% CI 71%-83%), with a cost of $15,697 Canadian dollars (CAD) per quality-adjusted life year (QALY) relative to usual care. Ablation for atrial fibrillation resulted in greater freedom from arrhythmia than medical treatment alone (RR 0.30; 95% CI 0.11-0.79), and downstream cost savings. Two technologies were effective in the prevention of chronic wounds and 8 technologies were effective in the management of chronic obstructive pulmonary disease, stroke, coronary artery disease, congestive heart failure or benign prostatic hyperplasia. Among these 10 technologies, all 5 analyses that reported incremental cost-effectiveness ratios were cost-effective based on a $50,000 (CAD) per QALY threshold. **CONCLUSIONS:** This review demonstrates that individual health technologies can be both effective and cost-effective in the overall management of chronic disease. Therefore health technologies can be a viable contributing factor to chronic disease management and should be considered as an integral component of community health care.

PHP119

SCORING INNOVATION AND CLINICAL BENEFIT FOR THE ALLOCATION OF FUNDS – A COMPARISON OF THE GERMAN AND FRENCH PRICING SYSTEMS

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OBJECTIVES: To compare the German (AMNOG) and French (ASMR) category scoring pricing systems; and to evaluate whether the two agencies have a similar interpretation of innovation and clinical benefit of the same drugs. Our results then allow us to theorize the future of European scoring systems. **METHODS:** A search of the G-BA website was conducted to identify all drug-related Health Technology Assessments (HTA) published between January 2011 and December 2012. Once a list of assessments was compiled, we searched the HAS website to identify the same drug HTAs published within the same time period. Then, for both agencies we identified and compared the methods in which they scored both innovation and clinical benefits of these drugs. To note: Germany (G-BA) provide AMNOG scorings from 1 (substantial benefit) to 6 (negative additional benefit), whilst France (HAS) provide ASMR scorings from I (major improvement) to V (no improvement). **RESULTS:** In this time period, sixteen HTAs were published by the G-BA, corresponding to 12 HTAs published by HAS. Upon observation of the scoring comparisons, only 3 of the 12 drugs were given the same scores by both agencies: Fampridine (AMNOG 5; ASMR V); Cabazitaxel (AMNOG 3; ASMR III); Linagliptin (AMNOG 5; ASMR V). For the remaining 12 drugs, there appeared to be little alignment in the scorings of innovation and clinical benefits: Vemurafenib (AMNOG 2; ASMR III), Vandetanib (5; IV), Belatacept (3; V), Apixaban (3; IV), Eribulin (6; IV), Collagenase clostridium histolyticum (5; no score), Abiraterone acetate (5; III), Fingolimod (3; IV) and Ticagrelor (2 and 5; IV). **CONCLUSIONS:** There does not seem to be a strong relationship between the criteria scoring of AMNOG and ASMR, demonstrating the heterogeneity of the European market. Whether increased HTA co-operation will align scoring more closely, or increased Value Based Pricing structures will drive divergence, is yet to be seen.

PHP120

AN INVESTIGATION INTO THE KEY DRIVERS INFLUENCING THE DECISION MAKING OF THE SCOTTISH MEDICINES CONSORTIUM

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OBJECTIVES: The main aim of this study was to identify significant implicit and explicit factors which play a role in decision making of the Scottish Medicines Consortium (SMC). Once these factors have been identified, the degree to which they influence the final decision will be ascertained. **METHODS:** A retrospective sample of submissions was taken from the SMC website. A bivariate statistical analysis was performed on the data extracted, allowing identification of the most fundamental drivers of an SMC decision. **RESULTS:** Between January 2006 and September 2011, 577 appraisals were made by the SMC. Of these appraisals, 27% accepted for full use, 30% were accepted for restricted use, whilst 43% of submissions were not recommended for use in Scotland. During this time period, the mean ICER for drugs accepted for use is £30,013 and for those that were not recommended for use the value was £38,132. Analysis of over 500 submissions to the SMC showed that a number of explicit, key drivers in line with SMC criteria were significant, including; the unofficial £30,000 ICER limit, the use of appropriate economic and clinical comparators, as well as robust demonstration of the economic case. Other key drivers which are more implicit, yet critical to decision making, were also shown to be significant. These included; the orphan status, submissions targeting paediatric populations and restrictions on the therapeutic scope of submissions placed by manufacturers. **CONCLUSIONS:** From a manufacturer point of view understanding the tendencies of the SMC is critical, as a firmer understanding of the key determinants of the SMC decision may lead to improved quality and robustness of future submissions. From the perspective of the SMC and the wider society, these insights will allow the public and the SMC to review the drivers of the decisions to establish whether they are in line with official criteria.

PHP122

EXCITE – A NEW COLLABORATIVE MODEL OF PRE-MARKET EVALUATION OF HEALTH TECHNOLOGIES

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OBJECTIVES: Many non-drug technologies with regulatory approval fail to be recommended for reimbursement. Reasons include low quality evidence or lack of relevance Excellence in Clinical Innovation and Technology Evaluation (EXCITE) is a collaboration between industry, government and academia to develop a harmonized pre-market evaluation that mitigates risk, improves adoption, and responds to system needs **METHODS:** EXCITE works with industry to evaluate evidence of efficacy and safety, cost effectiveness and adoption realities. It builds on Ontario's field evaluation experience. Structure: 1) Management board representing industry, government, academia and the Ontario Health Technology Advisory Committee (OHTAC); 2) Scientific collaboration of 7 Methodological Centres (MC) and 24 Academic Health Science Centres and a Quality Assurance Committee; and 3) Chief Scientific Officer and secretariat. Process: The management board prioritizes applications based on innovation, relevance, and commercialization. MCs develop a protocol and budget for clinical evaluation, systematic review, and an economic analysis. Human factors and usability analysis, and preference studies are offered. Consideration is underway for conditions of early adoption. Studies are funded by industry through MaRS, which fosters and commercializes innovation. **RESULTS:** Of 17 applications (year 1), 3 have commenced evaluation, 3 are in protocol development, discussions ongoing in 3 and one declined. Studies are designed to satisfy regulatory and reimbursement requirements and reflect complexities of adoption while maintaining high academic standards. Lessons learnt include a better understanding of the complexities of adoption and the benefit of endorsement in mitigating risk; limited funding for evaluations; tension between needs of industry and independence and objectivity of MCs; and intricacies of contract structures. **CONCLUSIONS:** EXCITE is a potential alternative to post-market HTA in Ontario, and may improve adoption in other jurisdictions. Expansion to a national and international scale will provide global reach for evaluated technologies. This is a potentially innovative and powerful model of early HTA.

PHP123

ROLE OF SUBGROUP ANALYSES FOR HEALTH TECHNOLOGY ASSESSMENTS

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OBJECTIVES: Cost effectiveness analyses play a critical role in determining coverage of novel drugs and devices. Increasingly, payers are demanding subgroup analyses to determine indications which would be covered by the national health system or insurance agency. **METHODS:** To understand and review trends in the use of subgroup cost effectiveness analysis, we analyzed NICE HTAs for products approved between 2011-2012. Manufacturer submissions for CEA were compared to final review and decision by HTA agency. Analogs were identified and case studies were developed to further understand the use of subgroup analyses and cost effectiveness models. **RESULTS:** Decisions made by NICE in 2011-2012 show increasing trends towards the use of subgroup analysis for determining indications for coverage by national payer bodies. Between 2011-2012, 80% of the assessments included subgroup analyses. Approximately half of them included cost effectiveness analyses for various subgroups. Interestingly, the ICER values estimated by NICE for the same subgroups showed a large variation (1X-3X fold difference) compared to ICER values estimated by manufacturers. Selected case studies highlighted that for several products, NICE is recommending treatments only for subgroups whose ICER values are within the cost effectiveness threshold. **CONCLUSIONS:** New products need robust broader population and subgroup analyses for insurance coverage.

HEALTH CARE USE & POLICY STUDIES – Patient Registries & Post-Marketing Studies

PHP124
REGISTRY OF PATIENT REGISTRIES (ROPR): PURPOSE, DESIGN AND EARLY EXPERIENCE

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OBJECTIVES: Patient registries are important tools for health care research. The goal of this project, sponsored by the Agency for Healthcare Research and Quality (AHRQ), is to design and implement the Registry of Patient Registries (RoPR), the first searchable, public database designed specifically to provide information about registries. The RoPR is integrated with ClinicalTrials.gov, supports research collaboration, reduces redundancy, and improves transparency in observational clinical research. **METHODS:** The RoPR consists of a registration system and a public search Web site. The registration system collects over forty data elements which define a registry profile. The search site serves as a central listing of registries and includes options to filter for relevant profiles. RoPR registration is integrated with ClinicalTrials.gov: users registering a study on ClinicalTrials.gov who designate it as a patient registry are presented with a pop-up window displaying the RoPR registration system. Users complete and submit the requested data elements, creating a registry profile in the RoPR that is linked to the ClinicalTrials.gov listing through a unique identifier, the NCT ID. **RESULTS:** The RoPR was launched on December 1, 2012. As of January 11, 2013, 54 new patient registries are registered on ClinicalTrials.gov. Twelve of these have been fully published in the RoPR, representing 21 different condition areas. Most are classified as disease/disorder/condition (67%), drug (33%), and/or procedure (33%) registries. Reported registry purposes include effectiveness (50%), safety or harm (42%), natural history of disease (42%) and clinical practice assessment (33%). A total of 67% of registry sponsors are open to being contacted for collaboration, data access, investigator or patient participation, or for information requests. **CONCLUSIONS:** The RoPR is a searchable Web site used by registry sponsors to publish information about registries and by members of the public to search for information about existing registries. Integration with ClinicialTrials.gov presents a user-friendly interface to encourage registration.

PHP125
POST-MARKETING REQUIREMENTS: AN OVERVIEW OF THE THERAPEUTIC AREAS TARGETED BY THE EMA AND THE FDA

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OBJECTIVES: Post-marketing *requirements* (PMRs) include studies and clinical trials that sponsors are *required*to conduct under one or more statutes or regulations. The objective of this research is to identify which therapeutic areas, and within these areas, which therapeutic indications have been subjected to the highest number of PMRs from the Food and Drug Administration (FDA, USA) and the European Medicines Agency (EMA, EU). **METHODS:** The Post-Marketing Requirements Database was used to explore requirements for post-approval studies published on the websites of the FDA and the EMA since 2005. The search was performed on January 2, 2013. **RESULTS:** The therapeutic area for which the EMA required the highest number of studies was “factors influencing health status and contact with health services” (n=36) for the indication “prophylaxis of influenza in a pandemic situation” (n=36). Within this indication, ten different products were concerned with Pandemrix and Cepalvan being the products with the highest number of studies requested (n=6 for each product). In comparison, the FDA had requested only 27 studies for the same therapeutic area, and neither Pandemrix nor Cepalvan were approved in the USA. The area for which the FDA requested the highest number of studies was “endocrine, nutritional and metabolic diseases” (n=80), and within this area, the more populated indication was “diabetes mellitus”(n=41). Within this indication, Onglyza, Byetta and Victoza were the products with the highest number of studies requested (n=4, 5, and 6 respectively). In comparison, the EMA had requested only 14 studies for the same area. Onglyza, Byetta and Victoza were approved in Europe but not subjected to PMRs. **CONCLUSIONS:** This brief review showed discrepancies in PMRs between the FDA and the EMA. More research is needed to explain these differences.

PHP126
CHALLENGES IN DEVELOPING AN OUTCOME MEASURES FRAMEWORK FOR PATIENT REGISTRIES

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OBJECTIVES: Patient registries are important tools for health care research, but variations in definitions of outcome measures and their data elements make it difficult to compare or link data from different registries. Standardizing outcome measures would help identify registries capturing similar information and promote collaboration, reduce redundancy, and improve efficiencies of new registries using standardized data elements. The goal of this project, sponsored by the Agency for Healthcare Research and Quality (AHRQ), is to develop a prototype of an Outcome Measures Framework (OMF) for use within the Registry of Patient Registries (RoPR) to collate and characterize the outcome measures currently used in patient registries. The long-term objective of the OMF is to support efforts to standardize outcome measures. **METHODS:** Stakeholders from a broad range of organizations (e.g., clinicians, registry sponsors, researchers, government agencies) were identified and invited to participate in a series of meetings to gather and refine the design requirements for the OMF. Requirements were also refined through user acceptance testing. Over 110 individuals participated in OMF design activities. **RESULTS:** Stakeholders identified several challenges necessary to address in designing the OMF. They want a framework that 1) distinguishes between outcome measures collected on a patient level and those collected or calculated on a population level; 2) describes the frequency or timeframe in which a particular outcome measure is collected; 3) identifies outcome measures that are clinically equivalent to each other and clearly displays this information; and 4) minimizes user burden, since participation in the RoPR is currently voluntary. **CONCLUSIONS:** By using a design process that solicited the opinions of a wide variety of stakeholders, several challenges were identified. These challenges were addressed in the design of the OMF prototype, and will require further clarification if the OMF is developed and implemented into a system such as the RoPR.

HEALTH CARE USE & POLICY STUDIES – Population Health

PHP127
RELATIVE IMPACT OF MULTIMORBID CHRONIC CONDITIONS ON HEALTH-RELATED QUALITY OF LIFE MEASURED BY THE EQ-5D

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OBJECTIVES: Multimorbidity has a negative impact on health-related quality of life (HRQL). Previous studies included only a limited number of frequent conditions and their combinations. The aim of this study was to analyse the relative impact of a large number of chronic conditions on overall HRQL in multimorbid patients. **METHODS:** This analysis is based on the MultiCare Cohort study, a multicenter, prospective cohort study of 3189 multimorbid primary care patients aged 65 to 85. The impact of 45 conditions on HRQL was analysed. The severity of the conditions was rated between 0 (insignificant) and 4 (very severe). The EQ-5D, a questionnaire consisting of 5 items (dimensions) and a visual-analogue-scale (EQ VAS) was employed to measure HRQL. Data were analyzed using multiple ordinary least squares regression and multiple logistic regression. **RESULTS:** Multimorbidity measured by a weighted count score was significantly associated with lower overall HRQL (EQ VAS). Parkinson´s disease had the most pronounced negative effect on overall HRQL (EQ VAS), followed by rheuma, depression, obesity and cardiac insufficiency. With regard to the individual EQ-5D dimensions, depression and obesity affected all five dimensions of the EQ-5D negatively except for the dimension anxiety/depression. Obesity had a positive effect on this dimension. Cardiac insufficiency was associated with three dimensions. The dimensions `self-care´ and `usual activities´ were most strongly affected by Parkinson´s disease. **CONCLUSIONS:** The overall HRQL of multimorbid patients decreases with an increasing count and severity of conditions. Parkinson´s disease, depression and obesity have the strongest impact on health-related quality of life.

PHP128
SELF-RATED HEALTH MEASURES WITH DIFFERENT REFERENCE POINTS AND MORTALITY

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OBJECTIVES: Self-rated health (SRH) has been shown to be a good predictor of mortality. However, there are mixed findings of the association between mortality and SRH measures with different reference points (i.e., with respect to either global or peer age group). This study assessed whether SRH measures with different reference frames influence the association of the SRH and mortality in old population. **METHODS:** We analyzed data from 2000-2005 Medical Expenditure Panel Survey (MEPS) respondents in Panel 5-7, aged 60 or over, linked to the National Death Index (NDI) through 2006. To test whether the SRH measures with different reference points were comparable measures to predict mortality, two SRH measures (global and age-comparative SRHs) were applied separately and concurrently. Cox proportional hazards model was conducted, adjusted for demographic and social characteristics. **RESULTS:** A total of 4787 respondents were included in the analysis. More respondents were likely to assess their health as excellent or very good on the age-comparative SRH measure than on the global SRH measure (excellent, 14.7% vs. 7.6%; very good, 28.6% vs. 25.8%, respectively). In the independent models, ‘poor’ SRH ratings were the strongest predictor of mortality. Poor global SRH ratings increased mortality risk by 5.06 times and poor age-comparative SRH rating increased mortality risk by 5.02 times compared to their respective excellent ratings. When two measures were concurrently analyzed in the relation to mortality risk, both measures significantly predicted mortality and poor global SRH ratings were the strongest predictor of mortality (Hazard ratio = 2.75; 95% CI = [1.694, 4.469]). **CONCLUSIONS:** In this study, both global and age-comparative SRH measures were associated with increased risk of mortality. However, we also found that the global SRH measure tended to have more predictive power than the age-comparative measure. Our findings imply that the different reference points may affect the association between SRH measures and mortality.